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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/308,237	05/21/1999	HIDENORI OHKI	0018-1052-0P	5890

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/22/2002

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/308,237

Applicant(s)

Ohki et al.

Examiner

Michael Borin

Art Unit

1631



- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Nov 23, 2001

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 18-46 is/are pending in the application.

4a) Of the above, claim(s) 23-40 and 43-46 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 18, 22, and 28-42 is/are rejected.

7) ☒ Claim(s) 19-21 is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

Art Unit: 1631

DETAILED ACTION

Continued examination under 37 CFR 1.114 after final rejection

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/28/01 has been entered.

Status of Claims

Amendment filed 9/28/01 is acknowledged. All previously pending claims, claims 2-9,11,13,16,17 are canceled. Claims 18-46 are added. Claims 18-46 are pending. As the claims drawn to products remain to stand rejected, claims 43-46 drawn to methods of making of making and using remain withdrawn from consideration, as being drawn to previously non-elected groups¹.

¹A cursory look at claims drawn to method of use indicated that the claims 44-46 will be

Art Unit: 1631

As per election of species, during the prosecution of the parent application the initially elected species were deemed allowable and the examination was extended to species where R_1 is 4-[5-(4-pentyloxyphenyl)izoxazol-3-yl]benzoyl, and then to species wherein R_1 is benzoyl substituted with piperazinyl substituted with phenyl(lower)alkyl having lower alkoxy and R_1 is benzoyl substituted with piperazinyl substituted with phenyl(lower)alkyl having cyclo(lower)alkyl. Even though the rejection of the latter is maintained hereby, examination was extended to address species wherein R_1 is benzoyl substituted with piperazinyl. The claims reading on the thus elected species are 18-22, 41,42. Claims 23-40 are not addressed in art rejections as drawn to non-elected species. Claims 23-40 are, however, addressed in rejections made under 35 U.S.C. 112, first and second paragraphs, to clarify technical issues before their examination on merits.

Claim Objections

Claim 18 contains a plurality of values for R_1 and is difficult to read as it contains two Markush subgroups first, followed by a plurality of single values. It is suggested that

subject iof the scope of enablement rejection as the only experimental data present in the specification (p. 30-32) demonstrate effect on only two microorganisms, *Candida* and *Pneumocystis*.

Art Unit: 1631

the values for R1 are presented as a Markush group "R₁ is a substituent selected from the group consisting of..."; then replace "or" with "and" before the ultimate member of the group.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18,22,28-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reason.

A. Claims 18,28, 41,42: It is not clear in claim 28 (and correspondent part of the base claim 18), whether the phrase " , and cyclo(lower)alkyl, " defines a separate substitution of piperidyl or it is a substitution of phenyl(lower)alkyl appearing together with, or as an alternative to lower alkoxy. For the purposes of rejections over prior art all of these possibilities are considered equally possible.

Art Unit: 1631

B. Claim 22 lacks antecedent basis as it recites "piperazinyl substituted with piperidyl having lower alkoxy". No such radical is claimed as R1 in the base claim 18. See also "new matter rejection" under 35 U.S.C. 112, first paragraph.

C. ~~Claim 29: First, there are three occurrences of the term "piperidyl" in the claim.~~

It is not clear whether the last occurrence relates to the first or the second occurrence. Second, the multiple variations and alternative of substitutions claimed make the scope of the claim unclear.

D. Claims 29-40: All these claims lack antecedent basis as they claim "piperidyl substituted with benzoyl substituted with .." (piperidyl, thiadiazolyl, etc). Such sequential substitution is not recited in the base claim. See also "new matter rejection" under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22,29-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way

Art Unit: 1631

as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 22 introduces new matter as it recites compounds having "piperazinyl substituted with piperidyl having lower alkoxy" as R1. There is no disclosure in the specification of such species.

Same in regard to claims 29-40 reciting "piperidyl substituted with benzoyl substituted with piperidyl" (or with thiadiazolyl, etc) as R1.

Claim Rejections - 35 USC § 103

Claims 18,22 are rejected under 35 U.S.C. 103(a) as anticipated by Ohki et al (WO 96/11210)

Ohki et al teach cyclic peptides of formula 1 which have antifungal activity and pharmaceutical compositions thereof. Radical R1 in the referenced compounds (which corresponds to R1 in the claimed compounds) can be a benzoyl substituted with piperazinyl, wherein the piperazinyl can be further substituted with phenyl having cycloalkyl. See example 70, p. 177. The only difference of the referenced compound from the instantly claimed compounds wherein R1 is benzoyl substituted

Art Unit: 1631

with piperazinyl having phenyl(lower)alkyl with cyclo(lower) alkyl is the absence of lower alkyl group on phenyl radical.

Further, Ohki teaches cyclic peptides of formula 1 wherein R1 is benzoyl substituted with piperazinyl substituted with phenyl having alkoxy. See example 105, p. 182. The only difference of the referenced compound from the instantly claimed compounds wherein R1 is benzoyl substituted with piperazinyl substituted with phenyl having (lower)alkoxy is that alkoxy group has 7 carbons, whereas specification defines (lower) alkyl as having up to 6 carbons (p. 9).

In both cases, the claimed and referenced compounds are homologs. Within the context of chemistry, unsubstituted compounds are similar to their homologue, lower alkyl (methyl) substituted compounds in the physical properties, i.e., structurally, and because of their structural similarity, it is generally predictive that their chemical properties will be similar. Because the adjacent homologs, lower alkyl compounds, would be expected to have similar physical and chemical properties as unsubstituted compounds, a high degree of predictability in producing a compound having the same physical and chemical properties would be expected when substituting H for lower alkyl group in a large compound. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

Art Unit: 1631

preferred compounds of WO 96/11210 such unsubstituted phenyl is replaced by (lower)alkylphenyl or C6 alkoxy is replaced with C7 alkoxy. Since one of ordinary skill in the art of general chemistry would have expected that such modifications would not change the properties of a compound in a significant way, one of ordinary skill in the art would have been motivated to make such a modification so as to obtain another preferred compound with the activity disclosed in WO 96/11210.

Claims 19-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Serial Number: 09/308237

Page 9

Art Unit: 1631

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 18, 2002

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.